UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAKE CHARLES DIVISION

TINA JOHNSON	§	
	§	
VS.	§	**CIVIL ACTION NO.** 2:10-CV-00404
	§	
TEVA PHARMACEUTICALS USA, INC., et al.	§	
	§	

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., QUALITEST PHARMACEUTICALS, INC., AND GENERICS BIDCO I, LLC'S REPLY IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS

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PRELIMINARY STATEMENT

As shown in the Motion for Judgment on the Pleadings ("Motion") filed on behalf of defendants Teva Pharmaceuticals USA, Inc.; Qualitest Pharmaceuticals, Inc., and Generics Bidco I, LLC (the "Generic Defendants"), although Plaintiff asserts various theories of liability in her Original Complaint ("Complaint"), the factual allegations all center around allegedly inadequate warnings and are preempted by federal law pursuant to *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011). An amendment of the Complaint to allege additional theories of liability that are not valid under the Louisiana Products Liability Act, and also are clearly preempted by federal law, would be futile. In her opposition, Plaintiff mischaracterizes the state of the case law since *Mensing*, which has dismissed an overwhelming number of identical lawsuits against generic drug manufacturers. The present case is indistinguishable from *Mensing* and the United States Court of Appeals for the Fifth Circuit's ruling in *Demahy*, both of which are binding authority on this Court. Plaintiffs' Complaint must be dismissed.

ARGUMENT

I. The Court Should Not Allow Plaintiff to Amend Her Complaint.

An amendment of Plaintiff's Complaint in this case would be futile. A Court should not grant leave to amend if "the movant has acted in bad faith or with a dilatory motive, granting the motion would cause prejudice, *or amendment would be futile*." *Jebaco, Inc. v. Harrah*'s *Operating Co., Inc.*, 587 F.3d 314, 322 (5th Cir. 2009) (emphasis added). Since her Louisiana Products Liability Act ("LPLA") claims fail in light of *Mensing*, Plaintiff requests in her Response in Opposition to Generic Defendants' Motion to Dismiss ("Opposition") that the Court lift the current stay to allow Plaintiff to file a motion for leave to file an amended complaint.

However, the allegations Plaintiff suggests she will add to an amended complaint are invalid under Louisiana law and preempted under federal law pursuant to *Mensing*.

As discussed at length in Section III of Generic Defendants' Motion for Judgment on the Pleadings ("Motion"), the alternative theories of liability not included in Plaintiff's Complaint, but set forth in Plaintiff's Brief on the Impact of *Mensing*, and most recently suggested in her Opposition, do not exist under Louisiana law. The LPLA forbids plaintiffs in products liability actions from pleading claims other than failure to warn, breach of express warranty, design defect, or construction or composition defect. Specifically, Plaintiff's "failure-to-communicate" and "failure-to-update" claims, which Plaintiff stresses in her Opposition, are not permitted under the LPLA. The Court should not permit Plaintiff to amend her Complaint to assert claims that exceed the scope of Louisiana state law. Even if Plaintiff could argue that her "failure-to-communicate" and "failure-to-update" theories expressed in her briefing could be shoehorned into the "failure-to-warn" claim under the LPLA, *Mensing* held that all failure-to-warn claims brought against generic drug defendants are preempted. 131 S. Ct. 2567. It would be futile to allow Plaintiff to amend her Complaint to assert allegations that are not valid claims in Louisiana, and, even if allowed to be pled under the LPLA, are preempted by federal law.

As Generic Defendants have thoroughly explained in Section III.C of their Motion, Plaintiff's argument that generic manufacturers have a duty to use additional methods of communication to provide warnings to physicians fails as a matter of law because Plaintiff's argument is contrary to *Mensing* and to federal regulations. (Mot. at 18-19.) Furthermore, Plaintiff ignores decisions from the United States Courts of Appeals for the Fifth, Sixth, and Eighth Circuits, and from various district courts, including the United States District Court for the Western District of Louisiana, rejecting that very argument. (*Id.* at 14-15); *see Morris v.*

Wyeth, Inc., No. 3:09-cv-854, 2011 WL 4973839, at *2 (W.D. La. Oct. 19, 2011), *app. pending*. In fact, the *Smith* plaintiffs made this very argument in their petition for rehearing and rehearing en banc, and the Sixth Circuit denied their petition, having "fully considered [this issue] upon the original submission and decision of the cases." *Smith v. Wyeth, Inc.*, No. 09-5460, slip op. (6th Cir. Nov. 22, 2011) (Ex. D to Motion). Furthermore, after the Sixth Circuit rejected the argument, the *Smith* plaintiffs forcefully argued a failure to communicate in their petition for *certiorari* to the United States Supreme Court. Petition for Writ of Certiorari, *Smith v. Wyeth, Inc.*, No. 11-1046, 2012 WL 598076 (Feb. 21, 2012). However, the Supreme Court recently denied plaintiffs' petition for *certiorari*. 566 U.S. -- , 2012 WL 592900 (Apr. 30, 2012).

Furthermore, Plaintiff's argument that Generic Defendants should be held liable for failing to update their generic metoclopramide labels to match the brand-name label was likewise put to rest in Generic Defendants' Motion. (Mot. § III.B.) Plaintiff's failure-to-update theory fails because, even if this claim did exist under the LPLA, it is no more than a failure-to-warn claim. (*Id.* at 14.) Moreover, it is barred by federal law, as it is as an attempt privately to enforce the provisions of the federal Food, Drug, and Cosmetic Act. (*Id.* at 14-15.) Plaintiff's Opposition ignores cases cited in Generic Defendants' Motion where the plaintiffs argued this same failure-to-update theory, but the courts dismissed all of the plaintiffs' claims as preempted. In fact, recently, the Supreme Court denied the *Smith* plaintiffs' petition for *certiorari* despite the plaintiffs' arguments therein that the generic metoclopramide manufacturers should be held liable for failing to update their label to match the brand manufacturer's label. 2012 WL 592900. It would be futile for this Court to allow Plaintiff to amend her Complaint to assert an alleged failure to update, as these claims are preempted pursuant to *Mensing* and to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is

the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.") (citing 21 U.S.C. § 337(a)).

Additionally, as discussed on pages 17-18 of Generic Defendants' Motion, while Plaintiff wishes to amend her Complaint to assert that Generic Defendants failed to communicate labeling changes to the medical community and consumers, or to update the label, she alleges in her current Complaint that the metoclopramide labeling remained inadequate. (*See, e.g.*, Compl. ¶¶ 3.04, 3.08.) Numerous district courts have dismissed lawsuits in which the plaintiffs made the same allegations finding that there is no duty to provide *inadequate* warnings. *See, e.g.*, *Morris v. Wyeth, Inc.,* No. 09-0854, 2012 WL 601455, at *4 (W.D. La. Feb. 23, 2012) (refusing to allow amendment because plaintiffs' new claims would be inconsistent with allegations in plaintiffs' complaint that label was inadequate until 2009); *Waguespack v. PLIVA USA, Inc.*, No. 10-692 (E.D. La. Nov. 3, 2011) (recognizing same inconsistency); *Bowman v. Wyeth, LLC*, No. 10-1946 (JNE/SER), 2012 WL 684116, at *7 (D. Minn. Mar. 2, 2012) (noting plaintiff "continues to contend that even the post-July 2004 Reglan warnings were inadequate," and holding "there is no duty for a manufacturer to provide an inadequate warning").

Other federal district courts have denied plaintiffs' requests to amend where the amendment would contradict plaintiffs' prior allegations or would be futile in light of *Mensing*. *See, e.g.*, *Morris*, 2012 WL 601455, at *4 ("[A] fifth amendment in this case would be futile because any claim based on the 2004 label would be inconsistent with Plaintiffs' assertion that all pre-2009 labeling failed to adequately warn."); *Moore v. Mylan, Inc.*, No. 1:11-CV-03037, -- F. Supp. 2d --, 2012 WL 123986, at *12 n.11 (N.D. Ga. Jan. 5, 2012) (denying leave to amend to allege a failure to communicate "because plaintiff's proposed claim is preempted," citing

Mensing and the federal regulations governing labeling). Likewise, this Court should deny Plaintiff's request for leave to amend her Complaint and grant Generic Defendants' Motion.

II. Plaintiff Mischaracterizes the State of the Case Law.

Plaintiff in her Opposition completely distorts the state of the case law since *Mensing* was decided. Contrary to Plaintiff's assertions, a widespread consensus has emerged in the courts in favor of dismissal of all plaintiffs' claims against generic drug defendants in light of *Mensing*. As explained in Section I of Generic Defendants' Motion, the Fifth, Sixth, and Eighth Circuit Courts of Appeal have all specifically dismissed generic metoclopramide lawsuits on the authority of *Mensing*. And the overwhelming majority of trial courts that have looked at these issues since *Mensing* have dismissed all claims.[1] "Plaintiff's contention that 'the vast majority of courts' are not dismissing similar claims across the country is belied by the case law." *Gross v. Pfizer, Inc*., No. 10-CV-00110-AW, 2012 U.S. Dist. LEXIS 11154, at *5 (D. Md. Jan. 27, 2012); *Bowman*, 2012 WL 684116, at *7 ("The sweeping language of the Supreme Court's opinion, as well as the Eighth Circuit's affirmation of the dismissal of all of Mensing's claims – even those claims not labeled as 'failure-to-warn' claims – lead this Court to find that all of Bowman's claims are preempted under the theory of conflict preemption. This Court's conclusion is in accordance with the tsunami of cases that have been decided since the Mensing decision."); *see also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL 2226 (E.D. Ky. Apr. 27, 2012) (denying plaintiffs' motion to amend court's earlier order dismissing claims against

[1] Approximately five dozen courts since *Mensing* have dismissed claims against generic defendants in full, including several MDL courts which have dismissed all of the plaintiffs' claims in the litigation against all generic defendants in one fell swoop. *See In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL 2226, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012); *In re: Pamidronate Prods. Liab. Litig.*, Nos. 09-MD-2120, 10-CV-1860, -- F. Supp. 2d --, 2012 WL 272889 (E.D.N.Y. Jan. 30, 2012); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243, Civ. No. 08-008, 2011 WL 5903623 (D.N.J. Nov. 21, 2011); *In re Accutane Prod. Liab. (Plevniak)*, MDL 1626-IBD, 2011 WL 6224546 (M.D. Fla. Nov. 9, 2011).

generic manufacturers as preempted so as to certify the ruling for interlocutory appeal because the court could not "conclude in good faith that there is a substantial grounds for difference of opinion regarding this ruling after *Mensing*") (Ex. A).

It is Plaintiff who fails to address decisions contrary to her position. Plaintiff argues that there was a "noticeable absence of precedent from this jurisdiction" in Generic Defendants' Motion. (Opp. at 4.) Yet Plaintiff has ignored that Generic Defendants' Motion was in part based on the Fifth Circuit's decision on remand in *Demahy v. Wyeth, Inc.*, which vacated the Eastern District of Louisiana's order (which had held that failure-to-warn claims are not preempted), and remanded for entry of judgment in favor of the generic drug manufacturer. *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011).[2]

Plaintiff attacks Generic Defendants' citation of fourteen Louisiana federal district court cases that have dismissed entire lawsuits against generic drug manufacturers pursuant to *Mensing*, because several of those motions to dismiss were not opposed by the plaintiffs in those cases. However, most of the Louisiana decisions on unopposed motions have been decisions where the courts, in addition to noting that the decisions were unopposed, specifically found merit in the generic defendants' preemption arguments.[3] Furthermore, other decisions were opposed, including the *Morris* case in this district with the same plaintiffs' counsel as this case.

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[2] Soon thereafter, consistent with the Fifth Circuit's mandate, the district court entered judgment in favor of the generic drug manufacturer defendant, and dismissed the plaintiff's suit with prejudice. *See Demahy v. Wyeth, Inc.*, No. 2:08-cv-03616, 2011 WL 5505399 (E.D. La. Aug. 30, 2011), *app. pending*.

[3] *See Boyer v. Wyeth, Inc.*, No. 2:09-cv-06123-SRD-DEK, slip op. (E.D. La. Jan. 11, 2012) (Ex. E to Motion); *Pellegrin v. Qualitest Pharm., Inc.*, No. 10-2125, 2012 WL 641967 (E.D. La. Jan. 10, 2012); *Barfield v. Wyeth, Inc.*, No. 5:09-cv-02012, 2012 WL 641948 (W.D. La. Jan. 4, 2012); *Stevens v. PLIVA, Inc.*, No. 6:10-0886, 2011 WL 6224569 (W.D. La. Dec. 2, 2011); *Richardson v. Wyeth, Inc.*, No. 10-0883, 2011 WL 5402184 (W.D. La. Nov. 7, 2011); *Guilbeau v. Wyeth Inc.*, No. 09-1652, 2011 WL 4948996 (W.D. La. Oct. 14, 2011); *Phillips v. Wyeth Inc*, No. 10-0882, 2011 WL 5826035 (W.D. La. Oct. 14, 2011); *LaBruyere v. Actavis, Inc.*, No. 09-6127, 2011 WL 5826018 (E.D. La. Oct. 4, 2011); *Brown v. Actavis Elizabeth*, *LLC,* No. 2:10 CV 00011-SRD-JCW, 2011 U.S. Dist. LEXIS 89393 (E.D. La. Aug. 10, 2011).

In support of her argument that she should be granted leave to amend, Plaintiff cites *Cooper v. Wyeth, Inc*, No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012), which allowed the failure-to-update and failure-to-communicate theories to move past the pleading stage.[4] The *Cooper* decision is inconsistent with the great weight of the case law.[5] Plaintiff also cites *Whitener v. PLIVA, Inc.*, No. 2:10-cv-01552, 2011 WL 6056546 (E.D. La. Dec. 6, 2011), which dismissed the plaintiffs' product liability claims against several generic metoclopramide manufacturers based on the fact that "the holding [in *Mensing*] is clear: state-law failure-to-warn claims against a generic drug manufacturer are preempted by federal law." The court allowed the plaintiffs leave to amend their complaint on a *narrow* issue of promotion for *use during pregnancy* but reiterated that claims over the warning provided are preempted. Plaintiff also cites dicta from the *Morris* court for the proposition that the Court should permit her to move forward with her failure-to-update theory.[6] However, Plaintiff neglects to note that the *Morris* Court held that *amending the complaint to allege any claim "based on the 2004 label would be inconsistent with Plaintiffs' assertion that all pre-2009 labeling failed to adequately warn*" and refused to allow an amendment to assert this claim. *Morris*, 2012 WL 601455, at *4 (emphasis added).

[4] The *Cooper* court dismissed most of the plaintiffs' claims against generic drug manufacturers. The court held (as in the *Demahy* case) that claims under LPLA based on metoclopramide's labeling are preempted by federal law. The court also held that any claims based on defendants' duty to conduct postmarketing surveillance "are undoubtedly preempted and must be dismissed." Likewise, failure to withdraw from the market claims are preempted: "If state law could *require* a generic drug manufacturer to wholly withdraw from the market . . . it *necessarily* must repudiate the label approved by the FDA. But that is precisely what *Mensing* teaches state law cannot do." 2011 WL 6056546, at *6. Additionally, the court held that when a generic drug product is designated by FDA as the RLD, the generic manufacturer does not hold NDA status or assume the burdens of the brand-name drug.

[5] *See* Generic Defendants' Motion at pages 19-22 listing many courts since *Mensing* that have rejected Plaintiff's failure-to-communicate theory as preempted.

[6] *See* Generic Defendants' Motion at pages 16-17 listing numerous courts since *Mensing* that have rejected Plaintiff's failure-to-update theory as preempted.

The Court should not be misled by Plaintiff's mischaracterization of the state of the case law since *Mensing*. The number of cases dismissing on the basis of preemption is overwhelming.

III. Plaintiff's LPLA Claims Are Preempted by Federal Law.

As explained thoroughly in Section II of Generic Defendant's Motion, Plaintiff's remaining LPLA claims are preempted and must be dismissed. The *Mensing* and *Demahy* complaints included the same allegations, which were held to be preempted. *Mensing* Complaint (Ex. B), Counts 1 and 2; *Demahy* Complaint (Ex. C), ¶¶ 28, 43, 44, 49 (sounding in breach of warranty), ¶ 38 (design defect). Furthermore, Plaintiff's breach of express warranty claim is based on a failure-to-warn theory and is preempted. (Mot. § II.A.) It does not allege that the Generic Defendants made any express warranties other than those contained in the FDA-approved package insert for metoclopramide. Also, many courts have dismissed these claims since *Mensing*.[7]

Plaintiff's design defect claim is also based on the warnings and is preempted, as discussed in Section II.B of Generic Defendants' Motion. Even if the claim were based on the actual design and formulation of generic metoclopramide, that kind of design defect claim also is preempted for the same reasons announced in *Mensing* and by the same federal law. (Mot. at 10-11.) Federal law forbids Generic Defendants from changing the design of a generic drug. 21 U.S.C. § 355(j)(2)(A) (requiring generic drugs to be the "same" as brand-name drugs); *see also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL 2226, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012) (dismissing as preempted plaintiffs' causes of action of strict liability

[7] *See* Generic Defendants' Motion at page 9 listing numerous post-*Mensing* decisions dismissing breach of express warranty claims as preempted.

design defect and negligent design, among others, and noting that these claims were "all based on the allegedly defective design of the drug, which the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change") (citing *Mensing*, 131 S. Ct. at 2575); *In re: Pamidronate Prods. Liab. Litig.*, Nos. 09-MD-2120(KAM)(SMG), 10-CV-1860(KAM)(SMG), 2012 WL 272889, at *3 (E.D.N.Y. Jan. 30, 2012) ("[T]he 'federal duty of "sameness,"' also applies in the context of generic drug design, and federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers.") (citing *Mensing*, 131 S. Ct. at 2575); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2283, Civ. No. 08-008 (GEB-LHG), 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011).[8]

As explained in Generic Defendants' Motion, the Sixth Circuit in *Smith v. Wyeth* rejected the plaintiffs' breach of warranty and design defect claims. Plaintiff argues in her Opposition that the Sixth Circuit did not actually find these claims preempted. However, and although the

[8] The Court of Appeals for the First Circuit in *Bartlett v. Mutual Pharmaceutical Co*., No. 10-2277, 2012 WL 1522004 (May 2, 2012), affirmed a jury verdict for the plaintiff in a generic drug lawsuit tried prior to *Mensing* on a design defect theory. The flaws in the court's opinion are numerous. The court acknowledged that it was impossible for the defendant generic drug manufacturer to change the design of its generic drug, just as it was impossible for it to change the generic drug label. Nonetheless, the court said that the generic drug manufacturer could avoid design defect liability by not selling the drug, though it recognized that this approach amounted to "second-guessing the FDA," and was at odds with the Supreme Court's *Mensing* decision. The *Bartlett* court perceived a "developing split in the lower courts, " but did not cite any decision agreeing with its interpretation, instead citing in support three decisions in which courts held design defect claims against generic drug manufacturers preempted. Two of the cases cited by the First Circuit are MDL rulings, *In re Darvocet*, 2012 WL 718618, and *In re Pamidronate*, 2012 WL 272889, in which all claims, under whatever theory, against generic drug manufacturers were dismissed. The third is a district court decision, *Lyman v. Pfizer, Inc.*, 2012 WL 368675 (D. Vt., Feb. 3, 2012), which expressly held the plaintiff's design defect claim against the defendant generic metoclopramide manufacturer preempted on the authority of *Mensing* because federal law required the generic drug be the same. In a gross understatement, the *Bartlett* Court cited the "tension" of its holding with the "rationale" of *Mensing*, and then urged the Supreme Court to address the preemption of design defect claims against generic drug manufacturers. The *Bartlett* decision cannot be squared with the *Mensing* decision or the Supreme Court's rejection of the *Mensing* plaintiffs' Petition for Rehearing, 2011 WL 2874547, at *2 (U.S. July 18, 2011), in which Petitioners argued that a claim that the generic manufacturers should have just stopped selling the drug should not be held preempted. *PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011). It should also be noted that *Bartlett* was a case governed by *New Hampshire* law. In this case, the *LPLA* provides the exclusive remedy for Plaintiff, and Plaintiff has not alleged the existence of an alternative design for generic metoclopramide, as is required under the LPLA, nor could she without contravening federal law; thus, Plaintiff has failed to plead the requisite elements for a design defect claim in Louisiana. (Mot. at 11.)

Smith plaintiffs made Plaintiff's exact same argument to the Sixth Circuit in their post-*Mensing* supplemental letter brief, 2011 WL 3662688, at *1-2 (6th Cir. Aug. 15, 2011), the Sixth Circuit made clear that it affirmed dismissal of *all* the plaintiffs' claims against generic drug manufacturers pursuant to *Mensing*: "The district court dismissed the plaintiffs' claims against the generic defendants on federal preemption grounds, finding a conflict between their tort claims and the federal regulation of generic drugs. . . . We find no error with regard to [the] ruling and affirm." 657 F.3d 420, 422 (6th Cir. 2011), *pet. for reh'g denied*; *see also id.* ("[T]he district court issued orders dismissing *all* claims and entered final judgment in favor of the defendants.") (emphasis added). The Sixth Circuit ruled in favor of preemption of *all* claims and did not so much as mention the plaintiffs' argument that design defect and breach of express warranty were not preempted. The same plaintiffs argued in their petition for writ of *certiorari* to the Supreme Court of the United States that the Court should grant the writ on the basis that their breach of express warranty and design defect claims survive *Mensing*. 2012 WL 598076. However, the Supreme Court denied the plaintiffs' petition.[9] 2012 WL 592900.

CONCLUSION

Generic Defendants respectfully request that the Court grant their Motion for Judgment on the Pleadings, and enter an Order dismissing the Complaint in its entirety, with prejudice, for failure to state a claim upon which relief can be granted.

[9] Furthermore, Plaintiff's reliance on *Halperin v. Merck, Sharpe & Dohme Corp.*, No. 11-c-9076, 2012 WL 1204728 (N.D. Ill. 2012) to support her design defect claim is misplaced. The design defect claim in *Halperin* is based upon the defendant's *derivative* liability as a distributor of a *brand* drug. The court held that every company in the chain of distribution is liable for design defect. In this case, the brand manufacturer was liable for the design defect (and this claim against a brand manufacturer is not affected by *Mensing*), and the distributor defendant was only liable derivatively. The court specifically notes that plaintiffs did not assert a claim against the defendant for improper design of the product by the defendant itself. As such, *Halperin* is inapposite.

Dated: May 8, 2012

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CERTIFICATE OF SERVICE

I certify that the foregoing Reply in Support of Motion for Judgment on the Pleadings was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to the following counsel, by operation of the court's electronic filing system, on this 8th day of May 2012:

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